REMARKS

Claims 1-3, 21, 22, 24 and 27 remain in this application. Claim 25 has been cancelled. Applicants respectfully request reconsideration in view of the above amendments and the following remarks.

Applicants' Response to 35 USC §102 Rejection over Landi

Claim 25 is rejected under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent No. 5,141,522 to Landi (hereinafter "Landi").

Applicants have cancelled claim 25, and thus, respectfully submit that this rejection has been obviated. Withdrawal of this Section 102(b) rejection is respectfully requested.

Applicants' Response to 35 U.S.C. §103 Rejection over Landi

Claim 22 was rejected under 35 U.S.C. §103(a) as allegedly being obvious over Landi. Applicants respectfully request reconsideration on the basis that Landi fails to teach or suggest Applicants' claim 22, and thus, fails to make out a *prima facie* case of obviousness.

The Examiner acknowledges that Landi fails to disclose a particle size of 5 to 100 microns. However, the Examiner contends that:

> Landi discloses pores which permit tissue growth as discussed above. Therefore, one of ordinary skill in the art would have recognized the utility of varying the particle size to obtain the desired ingrowth. Therefore, the ingrowth would be readily determined by through [sic] routine optimization of the particle size by one having ordinary skill in the art depending on the desired use of the end product as taught by Landi.
>
> It would therefore be obvious for one of ordinary skill in the art to vary the particle size in order to obtain the ingrowth, since the ingrowth would be readily determined through routine optimization by one having ordinary skill in the art depending on the

> desired end result as shown by Landi.
>
> (Office Action of 11/15/2006, at pages 3-4)
> (citations omitted).

As acknowledged by the Examiner in this same Office Action with respect to claims 1 and 3, "Landi fails to disclose an interpenetrating polymer network." (Office Action of 11/15/2006, at page 5). Applicants' claim 22 requires "an interpenetrating polymer network comprising a non-expanded PTFE matrix having no node and fibril structure." Because Landi does not disclose an interpenetrating polymer network (hereinafter "IPN"), the Examiner's burden of establishing a *prima facie* case of obviousness has not been met. "To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art." *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).

More specifically, Landi is directed to a composite material used for repairing mammalian tissue. The composite contains two biocompatible polymers. The first polymer is non-absorbable, unsintered PTFE, which is used in the composite as a reinforcing binder. The second polymer is a bioabsorbable polymer, which enhances tissue growth.

With respect to the first polymer component, Landi teaches that PTFE may be blended with a molten thermoplastic polymer, such as polymethylmethacrylate ("PMMA"). According to Landi, the PMMA component may be extracted from PTFE. Nowhere in Landi, however, is it disclosed, taught, or suggested that PMMA forms an IPN with PTFE.

As previously argued by Applicants in the Response dated January 5, 2004, an IPN is commonly understood in the art to mean a polymer containing two or more polymer networks, which are at least partially interlaced but not covalently bonded to each other. *See* IUPAC COMPENDIUM OF CHEMICAL TERMINOLOGY (2nd ed. 1997). More specifically, an IPN is a combination of two polymers in which at least one is synthesized and/or crosslinked in the

immediate presence of the other to form an interlaced network. *See*, e.g.,U.S. Patent No. 4,764,560 to Mitchell; Col. 1, lines 63-66. Accordingly, a mixture of two or more separate and independently pre-formed polymer networks is not an IPN. *See* IUPAC COMPENDIUM OF CHEMICAL TERMINOLOGY.

Landi discloses a mixture of PTFE and a molten thermoplastic polymer, i.e., PMMA. This is a mixture of two separate, and pre-formed, polymer networks. Nowhere in Landi is it disclosed, taught, or suggested that these two polymers are interlaced or interpenetrating in any manner. As commonly understood in the art, and defined above, Landi's combination of PTFE and PMMA cannot be considered an IPN.

In addition, Landi only discloses expanded PTFE having a fibrillar structure. Applicants' claim 22 specifically recites that the non-expanded PTFE has "no node and fibril structure." Nowhere in Landi is it disclosed, taught or suggested to use an IPN comprising PTFE having no node and fibril structure. Applicants' claim 22 requires an IPN of non-expanded PTFE having no node and fibril structure and another extractable polymer. Accordingly, Landi fails to render claim 22 *prima facie* obvious.

Applicants respectfully submit that claim 22 is patentable over Landi. Reconsideration and withdrawal of the Section 103 rejection is respectfully requested.

Applicants' Response to 35 U.S.C. §103 Rejection over Chau

Claim 24 is rejected under 35 U.S.C. §103(a) as allegedly being obvious over U.S. Patent No. 4,874,568 to Chau et al. (hereinafter "Chau"). Applicant respectfully request reconsideration on the basis that Chau fails to teach or suggest Applicants' claim 24, and thus, fails to make out a *prima facie* case of obviousness.

The Examiner acknowledges that Chau fails to disclose pores that permit tissue growth, but alleges that:

> Chau et al disclose the selection of leaching medium, and therefore pore size, depending on the desired use of the end product. Therefore, one of ordinary skill in the art would have recognized the utility of varying the pore size depending on the desired use of the end product.
>
> (Office Action of 11/15/2006, at page 4-5) (citations omitted).

At the outset, the Applicants would like to point out that claim 24 contains the transitional phrase "consisting essentially of". It is well established that such language "limits the scope of a claim to the specified materials or steps 'and those that do not materially affect the basic and novel characteristic(s)' of the claimed invention." *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original).

Chau discloses a process for preparing porous membranes to be used in ultrafiltration, distillation and substrates for composite membranes. The pores the Examiner references are created by: coextruding a plurality of layers of two different polymeric materials to form a laminate product; pulverizing the laminate product and recoextruding the pulverized product; pulverizing the recoextruded material and forming a melt composition into a thin, solid material; contacting the solid material with an extraction medium, whereby soluble materials are removed to leave a porous material; and then separating the extraction medium from the porous material. (Chau; claim 1). The layers of polymeric materials used in Chau are selected from two film-forming polymers. Therefore, Chau does not "consist essentially of" a non-expanded PTFE resin and a solid particulate polymeric compound that is incompatible with PTFE. As such, Chau cannot render claim 24 obvious.

Furthermore, although the Examiner alleges that one of ordinary skill in the art would have utilized the teachings of Chau to modify the pore size in order to have pores that permit tissue growth, the Applicants respectfully submit that such assertion is incorrect. Not only does

Chau disclose a wholly different material than that of the present invention, the pores sizes discussed in Chau are "determined by the thickness of layers or the number of passes through the coextrusion process rather than the extent of mixing, compounding or stretching." As such, one of ordinary skill in the art would not look to Chau to create the subject matter of the present invention.

Chau fails to disclose, teach or suggest a non-expanded PTFE resin having no node and fibril structure. The Examiner however, has alleged that Chau's inclusion of fluorocarbon in the list of film forming thermoplastic polymeric materials necessarily includes PTFE and further alleges that Chau does not disclose "a node and fibril structure or an expanded PTFE, and therefore discloses a non-expanded PTFE having no node or fibril structure." (Office Action of 11/15/2006, at page 4). Although there is no mention of expanding the polymers in Chau, it is stated that the film is "stretched to develop the desired void structure". It is well known to those skilled in the art of PTFE that stretching is synonymous to expansion and therefore Chau teaches use of an expanded PTFE.

Furthermore, Applicants would like to point out that Chau is classified in a wholly separate art unit from that of the present invention. Chau is classified as 264/49, titled Pore Forming, in situ. The present invention is classified as 623/1/13, titled Arterial Prosthesis. Chau is not a prosthesis and does not reference any type of use or compatibility with the body, which is the intent and purpose of the present invention.

Nothing in Chau would lead one of ordinary skill in the art to prepare the invention of the present claims, nor could you reach the invention of the present claims by the teachings of Chau. Accordingly, Chau fails to render claim 24 *prima facie* obvious.

Applicants respectfully submit that claim 24 is patentable over Chau. Reconsideration and withdrawal of the Section 103 rejection is respectfully requested.

Applicants' Response to 35 U.S.C. §103 Rejection over Landi in view of Nagasawa

Claims 1 and 3 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over Landi in view of U.S. Patent No. 5,723,526 to Nagasawa (hereinafter "Nagasawa"). Applicants respectfully request reconsideration on the basis that the combination of Landi and Nagasawa fails to teach or suggest Applicants' claims 1 and 3, and thus, fails to make out a *prima facie* case of obviousness.

In this rejection, the Examiner acknowledges that Landi fails to disclose an interpenetrating polymer network, but alleges that:

> Nagasawa teaches PTFE that is an interpenetrating polymer network for use in the making of a device for the purpose of obtaining a device that is superior in impact resistance. One of ordinary skill in the art would have therefore recognized the advantage of providing for the PTFE of Nagasawa in Landi, which comprises a device, depending on the desired impact resistance of the end product.
> It therefore would have been obvious for one of ordinary skill in the art at the time Applicant's invention was made to have provided for an interpenetrating polymer network in Landi in order to obtain a device that is superior in impact resistance as taught by Nagasawa.
>
> (Office Action of 11/15/2006, at page 5) (citations omitted).

The Examiner's assertions are respectfully traversed.

The Examiner has not provided a motivation to combine Landi and Nagasawa. As set forth in MPEP §2143.01, "[o]bviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art." The teachings of the references as a whole must be considered, not simply an element of one

reference to the exclusion of others. The primary reference must suggest or give motivation to combine with the secondary reference. "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." MPEP §2143.03 (citing *In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990) (emphasis in original). In the present application, there is no suggestion or motivation in the references themselves to combine the teachings of Landi and Nagasawa.

As discussed in detail above, Landi relates to an expanded PTFE having a fibrillar structure. As admitted by the Examiner, Landi fails to disclose an IPN. In addition, nowhere in Landi is an IPN comprising a non-expanded PTFE matrix having no node and fibril structure disclosed, taught or suggested. Furthermore, there is no motivation or suggestion to combine Landi with the teachings of Nagasawa.

The Examiner alleges Nagasawa teaches PTFE that is an IPN. Applicants respectfully submit that this assertion is incorrect. Nagasawa discloses "a resin composition consisting essentially of (a) an aromatic polycarbonate resin, (b) a thermoplastic graft copolymer obtained by grafting a diene rubber component with a vinyl cyanide compound and an aromatic vinyl compound, (c) a phosphoric acid ester, (d) a polytetrafluoroethylene, (e) a talc, and (f) a composite rubber having a network structure in which a polyorganosiloxane rubber component and a polyalkyl (meth)acrylate rubber component interpenetrate each other." As such, the PTFE of Nagasawa is a distinctly different element of the resin composition from the composite rubber having a network structure. Reading Nagasawa in its entirety connects the IPN to an wholly separate element of the resin composition. Therefore the PTFE is not an IPN and Nagasawa's teachings regarding an IPN are not relevant to Applicants' present claims.

Moreover, Nagasawa does not disclose, teach or suggest a PTFE having no node and fibril structure. The specification of Nagasawa explicitly states "a polytetrafluoroethylene is used as the component (d). A polytetrafluoroethylene having a fibril formability is

suitable...polytetrafluoroethylene having no fibril formability is unsuitable as the component (d)." (Nagasawa, col. 4, ll. 52-56). Fibril formability indicates that the PTFE is expanded. As such, Nagasawa actually teaches away from using a non-expanded PTFE matrix having no node and fibril structure. *See Tec Air, Inc. v. Denso Mfg. Michigan, Inc.*, 52 USPQ2d 1294, 1298 (Fed. Cir. 1999) (citing *In re Gurley*, 31 USPQ2d 1130, 1131 (Fed. Cir. 1994)) ("A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant or if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant."). In fact, PTFE having no fibril formability would destroy the intent and purpose of Nagasawa's invention.

Therefore, Nagasawa not only fails to provide for, but even teaches away from an IPN comprising a non-expanded PTFE having no node and fibril structure. As such, Nagasawa fails to cure the deficiencies of Landi in this regard. Accordingly, the combination of Landi and Nagasawa fails to render claims 1 and 3 *prima facie* obvious.

Applicants respectfully submit that claims 1 and 3 are patentable over Landi and Nagasawa, each taken alone or in combination. Reconsideration and withdrawal of the Section 103 rejection based on this combination is respectfully requested.

Applicants' Response to 35 U.S.C. §103 Rejection over Landi in view of Trescony

Claim 21 is rejected under 35 U.S.C. §103(a) as allegedly being obvious over Landi in view of U.S. Patent No. 5,607,464 to Trescony (hereinafter "Trescony"). Applicants respectfully request reconsideration on the basis that the cited combination fails to teach or suggest Applicants' claims, and hence fails to make out a *prima facie* case of obviousness.

With respect to claim 21, the Examiner acknowledges that Landi does not disclose a polymer comprising silicone. However, the Examiner asserts that:

> Trescony et al teach a vascular graft comprising PTFE and silicone for the purposes of obtaining a vascular graft having kink resistance. One of ordinary skill in the art would therefore have recognized the advantage of providing for the silicone of Trescony et al in Landi, which comprises PTFE, depending on the desired kink resistance of the end product.
> It therefore would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to have provided for a silicone in Landi in order to obtain a vascular graft having kink resistance as taught by Trescony et al.
>
> (Office Action of 11/11/2006, at page 6) (citations omitted).

The Examiner's assertions are respectfully traversed.

The Examiner has not provided a motivation to combine Landi and Trescony. The teachings of the references as a whole must be considered, not simply an element of one reference to the exclusion of others. The primary reference must suggest or give motivation to combine with the secondary reference. "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." MPEP §2143.03 (citing *In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990) (emphasis in original). In the present application, there is no suggestion or motivation in the references themselves to combine the teachings of Landi and Trescony.

Landi relates to an expanded PTFE having a fibrillar structure and fails to disclose an IPN. Nowhere in Landi is an IPN comprising a non-expanded PTFE matrix having no node and fibril structure disclosed, taught or suggested. Moreover, there is no motivation or suggestion to combine Landi with the teachings of Trescony.

As discussed in detail above, Landi does not disclose, teach or suggest an IPN comprising a non-expanded PTFE matrix having no node and fibril structure. Trescony was merely cited for its disclosure of silicone and fails to cure the deficiencies of Landi. Accordingly, the combination of Landi and Trescony fails to render claims 21 *prima facie* obvious.

Applicants respectfully submit that claims 21 is patentable over Landi and Trescony, each taken alone or in combination. Reconsideration and withdrawal of the Section 103 rejection based on this combination is respectfully requested.

Applicants' Response to 35 U.S.C. §103 Rejection over Chau in view of Trescony

Claim 27 has been rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Chau in view of Trescony. Applicants respectfully request reconsideration on the basis that the combination of references fails to teach or suggest Applicants' claim 27, and thus, fails to make out a *prima facie* case of obviousness.

The Examiner acknowledges that Chau fails to disclose a polymer comprising a silicone. However, the Examiner alleges that

> Trescony et al teach an extrudate comprising PTFE and silicone for the purposes of obtaining an extrudate having kink resistance. One of ordinary skill in the art would therefore have recognized the advantage of providing for the silicone of Trescony et al in Chau et al, which comprises PTFE, depending on the desired kink resistance of the end product.
> It therefore would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to have provided for a silicone in Chau in order to obtain an extrudate having kink resistance as taught by Trescony et al.
>
> (Office Action of 11/11/2006, at pages 6-7) (citations omitted).

The Examiner's assertions are respectfully traversed.

The Examiner has not provided a motivation to combine Chau and Trescony. The teachings of the references as a whole must be considered, not simply an element of one reference to the exclusion of others. The primary reference must suggest or give motivation to combine with the secondary reference. "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." MPEP §2143.03 (citing *In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990) (emphasis in original). In the present application, there is no suggestion or motivation in the references themselves to combine the teachings of Chau and Trescony. Moreover, even if combined, the references would not arrive at the present invention.

As discussed in detail above, Chau relates to a process for preparing porous membranes to be used in ultrafiltration, distillation and substrates for composite membranes. Nowhere in Chau is a medical device which "consists essentially of" a non-expannded PTFE resin and a solid particulate polymeric compound that is incompatible with PTFE disclosed, taught or suggested. Moreover, there is no motivation or suggestion to combine Chau with the teachings of Trescony. Chau fails to disclose, teach or suggest a non-expanded PTFE resin having no node and fibril structure. Trescony was merely cited for its disclosure of a polymer comprising silicone and fails to cure the deficiencies of Chau in this regard. Accordingly, the combination of Chau and Trescony fails to render claims 27 *prima facie* obvious.

Applicants respectfully submit that claims 27 is patentable over Chau and Trescony, each taken alone or in combination. Reconsideration and withdrawal of the Section 103 rejection based on this combination is respectfully requested.

Applicants' Response to 35 U.S.C. §103 Rejection over Landi in view of Nagasawa and further in view of Chuter

Claim 2 has been rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over

Landi in view of Nagasawa and further in view of U.S. Patent No. 6,293,969 to Chuter (hereinafter "Chuter"). Applicants respectfully request reconsideration on the basis that the combination of references fails to teach or suggest Applicants' claim 2, and thus, fails to make out a *prima facie* case of obviousness.

The Examiner acknowledges that Landi and Nagasawa fail to disclose a radially distensible stent positioned axially about the tubular extrudate. However, the Examiner alleges that:

> Chuter teaches a porous PTFE comprised in first and second stents with one stent positioned about the other stent for the purpose of obtaining a stent which is biologically inert. One of ordinary skill in the art would therefore have recognized the advantage of providing for the stent of Chuter in Landi and Nagasawa, which comprises PTFE, depending on the desired inertness of the end product.
> It therefore would have been obvious for one of ordinary skill in the art at the time Applicant's invention was made to have provided for a stent, therefore radially distensible, positioned axially about the tubular extrudate in Landi and Nagasawa in order to obtain a stent which is biologically inert as taught by Chuter.
>
> (Office Action of 11/15/2006, at page 7) (citations omitted).

As discussed in detail above, neither Landi nor Nagasawa discloses, teaches or suggests an IPN comprising a non-expanded PTFE matrix having no node and fibril structure. Chuter was merely cited for its disclosure of a porous PTFE comprised in first and second stents and fails to cure the deficiencies of Landi and Nagasawa in this regard. Accordingly, the combination of Landi, Nagasawa and Chuter fails to render claim 2 *prima facie* obvious.

Applicants respectfully submit that claims 2 is patentable over Landi, Nagasawa and Chuter, each taken alone or in combination. Reconsideration and withdrawal of the Section 103

rejection based on this combination is respectfully requested.

Having responded in full to the present Office Action, it is respectfully submitted that the application is in condition for allowance. Favorable action thereon is respectfully solicited.

The Commissioner is hereby authorized to charge payment of any additional fees associated with this communication, or credit any overpayment, to Deposit Account No. 08-2461. Such authorization includes authorization to charge fees for extensions of time, if any, under 37 C.F.R § 1.17 and also should be treated as a constructive petition for an extension of time in this reply or any future reply pursuant to 37 C.F.R. § 1.136.

Should the Examiner have any questions or comments concerning the above, the Examiner is respectfully invited to contact the undersigned attorney at the telephone number given below.

Respectfully submitted,

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